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February 12, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/635818
For: *COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION
OF ENDOGENOUS GENES*
Inventors: Harrington, John J. *et al.*
Filed: August 5, 2003
Our Ref. No.: ATX-007CP4DV13CN

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form SB/08; and
3. A Return Postcard.

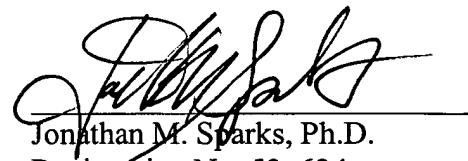
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February 12, 2004

Jonathan M. Sparks, Ph.D., Reg. No. 53, 624

Respectfully submitted,
LAHIVE & COCKFIELD, LLP


Jonathan M. Sparks, Ph.D.
Registration No. 53, 624
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Harrington, John J. *et al.*

Serial No.: 10/635818

Filed: August 5, 2003

For: *COMPOSITIONS AND METHODS FOR NON-TARGETED ACTIVATION OF ENDOGENOUS GENES*

Attorney Docket No.: ATX-007CP4DV13CN

Group Art Unit: 1645

Examiner: Not Assigned

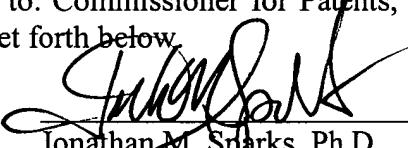
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Date of Signature and of Mail Deposit

By: 

Jonathan M. Sparks, Ph.D.
Registration No. 53, 624
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. The present application is a Continuation application of U.S. Application No. 09/513,575, filed February 25, 2000 (Attorney Docket No. ATX-007CP4DV13), which is a Divisional application of 09/276,820, filed March 26, 1999 (Attorney Docket No. ATX-007CP4). All references listed on the enclosed PTO Form SB/08 have been previously cited by or

submitted to the Office in the prior applications, and, in accordance with 37 CFR §1.98(d), copies of the references are not enclosed but will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP



Jonathan M. Sparks, Ph.D.
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Date: February 12, 2004

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Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/635818
<i>(Use as many sheets as necessary)</i>				Filing Date	August 5, 2003
				First Named Inventor	Harrington, John J. et al.
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	1	of	7	Attorney Docket Number	ATX-007CP4DV13CN

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A1		5,024,939	06-18-1991	Gorman	
A2		5,272,071	12-21-1993	Chappel	
A3		5,547,933	08-20-1996	Lin	
A4		5,561,053	10-01-1996	Crowley	
A5		5,578,461	11-26-1996	Sherwin et al.	
A6		5,580,734	12-03-1996	Treco et al.	
A7		5,618,698	04-08-1997	Lin	
A8		5,621,080	04-15-1997	Lin	
A9		5,629,159	05-13-1997	Anderson	
A10		5,641,670	06-24-1997	Treco et al.	
A11		5,677,170	10-14-1997	Devine et al.	
A12		5,683,905	11-04-1997	Capon et al.	
A13		5,688,679	11-18-1997	Powell	
A14		5,707,830	01-13-1998	Calos	
A15		5,728,551	03-17-1998	Devine et al.	
A16		5,733,746	03-31-1998	Treco et al.	
A17		5,733,761	03-31-1998	Treco et al.	
A18		5,783,385	07-21-1998	Treco et al.	
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A20		5,830,698	11-03-1998	Reff et al.	
A21		5,843,772	12-01-1998	Devine et al.	
A22		6,136,566	10-24-2000	Lexicon Graphics Inc.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
A23		WO 90/14092	11-29-1990	Cell Genesys, Inc.	
A24		WO 91/01140	02-07-1991	Cell Genesys, Inc.	
A25		WO 91/06667	05-16-1991	Cell Genesys, Inc.	
A26		WO 92/19255	11-12-1992	Cell Genesys, Inc.	
A27		WO 92/20808	11-26-1992	Cell Genesys, Inc.	
A28		WO 93/09222	05-13-1993	Transkaryotic Therapies, Inc.	
A29		WO 94/12650	06-09-1994	Transkaryotic Therapies, Inc.	
A30		AU 71893/94	06-30-1994	Odile Cohen-Haguenauer	

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Sheet	2	of	7	Attorney Docket Number	ATX-007CP4DV13CN

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	B1	FR 2 707 091	01-06-1995	Odile Cohen-Haguenauer	
	B2	WO 95/31560	11-23-1995	Transkaryotic Therapies, Inc.	
	B3	WO 96/04391	02-15-1996	Genentech, Inc.	
	B4	WO 96/29411	09-26-1996	Transkaryotic Therapies, Inc.	
	B5	EP 0 742 285 A1	11-13-1996	Rijksuniversiteit Leiden	
	B6	WO 98/12337	03-26-1998	Chiron Corporation	
	B7	WO 98/14614 A1	04-09-1998	Lexicon Genetics Incorporated	
	B8	WO 99/07389 A1	02-18-1999	Lexicon Genetics Incorporated	
	B9	WO 99/15650 A1	04-01-1999	Athersys, Inc.	
	B10	WO 99/50426	10-07-1999	Lexicon Genetics Incorporated	

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	B11	Auch, D., and Reth, M., "Exon trap cloning: using PCR to rapidly detect and clone exons from genomic DNA fragments," <i>Nucl. Acids Res.</i> 25:6743-6744 (1990).			
	B12	Avouustin, P., et al., "Non-homologous recombination within the Major Histocompatibility Complex creates a transcribed hybrid sequence," <i>Mammalian Genome</i> 5(12): 771 -776 (1994).			
	B13	Barker, C.S., et al., "Activation of the Prolactin Receptor Gene by Promoter Insertion in a Moloney Murine Leukemia Virus- Induced Rat Thymoma," <i>J. Virol.</i> 66(11):6763-6768 (1992).			
	B14	Black, A.C., et al., "HTLV-II Rex Binding and Activity Requires an Intact Splice Donor Site and a Specific RNA Secondary Structure," <i>AIDS Res. & Human Retroviruses</i> 5:870 (1992).			
	B15	Brikun, I., et al., "Analysis of CRP-CytR Interactions at the <i>Escherichia coli</i> <i>udp</i> Promoter," <i>J. Bacteriology</i> 178(6):1614-1622 (March 1996).			
	B16	Buckler, A.J., et al., "Exon amplification: A strategy to isolate mammalian genes based on RNA-splicing," <i>Proc. Natl. Acad. Sci. USA</i> 95:4005-4009 (1991).			

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	C1	Butturini, A., et al., "Oncogenes in Human Leukemias," <i>Acta Haematologica</i> 78(Suppl. 1):2-10 (1987).			
	C2	Butturini, A., and Gale, R.P., "Oncogenes and Human Leukemias," <i>Intl. J. Cell Cloning</i> 6(1):2-24 (1988).			
	C3	Chakraborty, A.K., et al., "Transforming function of proto-ras genes depends on heterologous AR 4 promoters and is enhanced by specific point mutations," <i>Proc. Natl. Acad. Sci. USA</i> 88:2217-2221 (1991).			
	C4	Chang, W., et al., "Enrichment of Insertional Mutants Following Retrovirus Gene Trap Selection," <i>Virol.</i> 193:737-747 (1993).			
	C5	Chow, W.-Y., and Berg, D.E., "Tn5tac1, a derivative of transposon Tn5 that generates conditional mutations," <i>Proc. Natl. Acad. Sci. USA</i> 85:6468-6472 (1988).			
	C6	Church, D.M., et al., "Isolation of genes from complex sources of mammalian genomic DNA using exon amplification," <i>Nature Genetics</i> 6:98-105 (1994).			
	C7	Crabb, B.S., and Cowman, A.F., "Characterization of promoters and stable transfection by homologous and nonhomologous recombination in <i>Plasmodium falciparum</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 93:7289-7294 (July 1996).			
	C8	Datson, N.A., et al., "Specific isolation of 3'-terminal exons of human genes by exon trapping," <i>Nucl. Acids Res.</i> 22(20):4148-4153 (1994).			
	C9	Datson, N.A., et al., "Scanning for genes in large genomic regions: cosmid-based exon trapping of multiple exons in a single product," <i>Nucl. Acids Res.</i> 24:1105-1111 (March 1996).			
	C10	De Benedetti, A., and Rhoads, R.E., "A novel BK virus-based episomal vector for expression of foreign genes in mammalian cells," <i>Nucl. Acids Res.</i> 19:1925-1931 (1991).			
	C11	Dickson, C., et al., "Tumorigenesis by Mouse Mammary Tumor Virus: Proviral Activation of a Cellular Gene in the Common Integration Region <i>int-2</i> ," <i>Cell</i> 37:529-536 (1984).			
	C12	Dostatni, N., et al., "Use of Retroviral Vectors for Mapping of Splice Sites in Cottontail Rabbit - Papillomavirus," <i>J. Gen. Viro.</i> 69:3093-3100 (1988).			
	C13	Duesberg, P.H., et al., "Cancer Genes by Non-Homologous Recombination," In: <i>Boundaries between 7 Promotion and Progression during Carcinogenesis</i> , Sudilovsky, O., et al., eds., Plenum Press, New York, NY, pp. 197-211 (1991).			
	C14	Duyk, G.M., et al., "Exon trapping: A genetic screen to identify candidate transcribed sequences - in cloned mammalian genomic DNA," <i>Proc. Natl. Acad. Sci. USA</i> 87:8995-8999 (1990).			
	C15	Frankel, W., et al., "Retroviral insertional mutagenesis of a target allele in a heterozygous murine cell line," <i>Proc. Natl. Acad. Sci. USA</i> 82:6600-6604 (1985).			
	C16	Fujisawa, J.-I., et al., "Functional activation of the long terminal repeat of human T-cell leukemia virus type I by a trans-acting factor," <i>Proc. Natl. Acad. Sci. USA</i> 82:2277-2281 (1985).			

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NON PATENT LITERATURE DOCUMENTS						
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		T ²				
	D1	Fung, Y.-K.T., et al., "Activation of the Cellular Oncogene <i>c-erbB</i> by LTR Insertion: Molecular Basis for Induction of Erythroblastosis by Avian Leukosis Virus," <i>Cell</i> 33:357-368 (1983).				
	D2	Goff, S.P., "Gene Isolation by Retroviral Tagging," <i>Meth. Enzymology</i> 152:469-481 (1987).				
	D3	Hay, Bruce A., et al., "P Element Insertion-Dependent Gene Activation In The Drosophila Eye," <i>Proc. Natl. Acad. Sci. USA</i> , 94:5195-5200 (May 1997)				
	D4	Hayward, W.S., et al., "Activation of a cellular <i>onc</i> gene by promoter insertion in ALV-induced lymphoid leukosis," <i>Nature</i> 290:475-480 (1981).				
	D5	Jackson, I.J., "A reappraisal of non-consensus mRNA splice sites," <i>Nucl. Acids Res.</i> 19(14):3795-3798 (1991).				
	D6	Joshi, S., "A Putative Approach for Cloning 'Silent' Genes Using Retroviral Vectors," <i>Med. Hypoth.</i> 36:242-245 (1991).				
	D7	Joyner, A.L., "Gene Targeting and Gene Trap Screens Using Embryonic Stem Cells: New Approaches to Mammalian Development," <i>BioEssays</i> 13:649-656 (1991).				
	D8	Junejo, F., et al., "Sequence analysis of the herpes simplex virus type 1 strain 17 variants 1704, 1705 and 1706 with respect to their origin and effect on the latency-associated transcript sequence," <i>J. Gen. Viro.</i> 72:2311-2315 (1991).				
	D9	Kaufman. <i>Short Protocols in Molecular Biology</i> , ed. Ausubel et al. John Wiley & Sons, Inc. 1995, pages 16-58-16-60.				
	D10	King, W., et al., "Insertion Mutagenesis of Embryonal Carcinoma Cells by Retroviruses," <i>Science</i> 228:554-558 (1985).				
	D11	Kreissig, S., et al., "Expression of peptides encoded by exons in cloned mammalian DNA," <i>Nucl. Acids Res.</i> 24:4358-4359 (November 1996).				
	D12	Lemay, G., and Jolicoeur, P., "Rearrangement of a DNA sequence homologous to a cell-virus junction fragment in several Moloney murine leukemia virus- induced rat thymomas," <i>Proc. Natl. Acad. Sci. USA</i> 81:38-42 (1984).				
	D13	Liang, Y., et al., "Effects of Alternate RNA Splicing on Glucokinase Isoform Activities in the Pancreatic Islet, Liver, and Pituitary," <i>J. Biol. Chem.</i> 266(11):6999-7007 (1991).				
	D14	Lih, C.-J., et al., "Rapid identification and isolation of transcriptionally active regions from mouse genomes," <i>Gene</i> 164:289-294 (1995).				
	D15	Liu, Z., et al., "The E6 Gene of Human Papillomavirus Type 16 Is Sufficient for Transformation of Baby Rat Kidney Cells in Cotransfection with Activated Ha-ras," <i>Virology</i> 201:388-396 (1994).				
	D16	Mölders, H., et al., "Integration of transfected LTR sequences into the <i>c-raf</i> proto-oncogene: activation by promoter insertion," <i>EMBO J.</i> 4(3):693-698 (1985).				
	D17	Moore, R., et al., "Sequence, topography and protein coding potential of mouse <i>int-2</i> : a putative oncogene activated by mouse mammary tumour virus," <i>EMBO J.</i> 5(5):919-924 (1986).				

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E1		Müller, R., and Müller, D., "Co-transfection of normal NIH/3T3 DNA and retroviral LTR sequences: a novel strategy for the detection of potential c-onc genes," <i>EMBO J.</i> 3(5):1121-1127 (1984).	
E2		Muth, K., et al. "Disruption of Genes Regulated During Hematopoietic Differentiation of Mouse Embryonic Stem Cells," <i>Develop. Dynamics</i> 212:277-283 (June 1998).	
E3		Neel, B.C., et al., "Molecular Analysis of the c-myc Locus in Normal Tissue and in Avian Leukosis Virus-Induced Lymphomas," <i>J. Virol.</i> 44(1): 158-166 (1982).	
E4		Nicolas, J.-F., and Rubenstein, J.L.R., "Retroviral Vectors," In: <u>Vectors: A Survey of Molecular Cloning Vectors and Their Uses</u> , Rodriguez, R.L., et al., eds., Butterworths Publs., Stoneham, MA, pp. 493-513 (1988).	
E5		Nilsen, T.W., et al., "c-erbB Activation in ALV-Induced Erythroblastosis: Novel RNA Processing 15 and Promoter Insertion Result in Expression of an Amino-Truncated EGF Receptor," <i>Cell</i> 41:719-726 (1985).	
E6		Niwa, H., et al., "An Efficient Gene-Trap Method Using Poly A Trap Vectors and Characterization of Gene-Trap Events," <i>J. Biochem.</i> 113:343-349 (1993).	
E7		Nottenburg, C., and Varmus, H.E., "Features of the Chicken c-myc Gene That Influence the 15 Structure of c-myc RNA in Normal Cells and Bursal Lymphomas," <i>Mol. Cell. Biol.</i> 6(8): 2800-2806 (1986).	
E8		Nouvel, P., "The mammalian genome shaping activity of reverse transcriptase," <i>Genetica</i> 93:191-201 (1994).	
E9		Nusse, R., "The activation of cellular oncogenes by retroviral insertion," <i>Trends in Genetics</i> 2:244-247 (1986).	
E10		Nusse, R., and Bemis, A., "Cellular Oncogene Activation by Insertion of Retroviral DNA; Genes Identified by Proivirus Tagging," In: <u>Cellular Oncogenes Activation</u> , Klein, G., ed., Marcel Dekker, Inc., New York, NY, pp. 95-119 (1988).	
E11		Payne, G.S., et al., "Multiple arrangements of viral DNA and an activated host oncogene in bursal lymphomas," <i>Nature</i> 295:209-215 (1982).	
E12		Peters, G., et al., "Tumorigenesis by Mouse Mammary Tumor Virus: Evidence for a Common Region for Proivirus Integration in Mammary Tumors," <i>Cell</i> 33:369-377 (1983).	
E13		Petitclerc, D. et al., "The effect of various introns and transcription terminators on the efficiency of expression vectors in various cultured cell lines and in the mammary gland of transgenic mice," <i>J. Biotechnol.</i> 40:169-178 (1995).	
E14		Reinhart, T.A., et al., "RNA Splice Site Utilization by Simian Immunodeficiency Viruses Derived from Sooty Mangabey Monkeys," <i>Virology</i> 224:338-344 (October 1, 1996).	

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				Application Number	10/635818
				Filing Date	August 5, 2003
				First Named Inventor	Harrington, John J. <i>et al.</i>
				Art Unit	1645
				Examiner Name	Not Yet Assigned
Sheet	6	of	7	Attorney Docket Number	ATX-007CP4DV13CN

NON PATENT LITERATURE DOCUMENTS				
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	F1	Robinson, W.S., "Molecular Events in the Pathogenesis of Hepadnavirus-Associated Hepatocellular Carcinoma," <i>Annu. Rev. Med.</i> 45:297-323 (1994).		
	F2	Salminen, M., <i>et al.</i> , "Efficient Poly A Trap Approach Allows the Capture of Genes Specifically Active in Differentiated Embryonic Stem Cells and in Mouse Embryos," <i>Develop. Dynamics</i> 212:326-333 (June 1998).		
	F3	Segal, D., <i>et al.</i> , "Genetic Transformation of <i>Drosophila</i> Cells in Culture by P Element-Mediated Transposition," <i>Somatic Cell and Mol. Genetics</i> 22 (2):159- 165 (March 1996).		
	F4	Shen-Ong, G.L.C., <i>et al.</i> , "Activation of the c-myb Locus by Viral Insertional Mutagenesis in Plasmacytoid Lymphosarcomas," <i>Science</i> 226:1077-1080 (1984).		
	F5	Shen-Ong, G.L.C., <i>et al.</i> , "Two Modes of c-myb Activation in Virus-Induced Mouse Myeloid Tumors," <i>Mol. Cell. Biol.</i> 6(2):380-392 (1986).		
	F6	Shin, S., and Steffen, D.L., "Frequent activation of the lck gene by promoter insertion and aberrant splicing in murine leukemia virus- induced rat lymphomas," <i>Oncogene</i> 5:141-149 (1993).		
	F7	Simpson, K., <i>et al.</i> , "Stable Episomal Maintenance of Yeast Artificial Chromosomes in Human Cells," <i>Mol. Cell. Biol.</i> 16:5117-5126 (September 1996).		
	F8	Stary, A., and Sarasin, A., "Simian virus 40 (SV40) large T antigen-dependent amplification of an 20 Epstein-Barr virus-SV40 hybrid shuttle vector integrated into the human HeLa cell genome," <i>J. Gen. Virol.</i> 73:1679-1685 (1992).		
	F9	Steffen, D., "Provirus are adjacent to c-myc in some murine leukemia virus-induced lymphomas," <i>Proc. Natl. Acad. Sci. USA</i> 57:2097-2101 (1984).		
	F10	Sun, T.-Q., <i>et al.</i> , "Human artificial episomal chromosomes for cloning large DNA fragments in human cells," <i>Nature Genetics</i> 8:33-41 (1994).		
	F11	Takami, Y., <i>et al.</i> , "Cloning and Characterization of Human Papillomavirus Type 52 From Cervical Carcinoma in Indonesia," <i>Int. J. Cancer</i> 48:516-522 (1991).		
	F12	Tashiro, S., <i>et al.</i> , "Identification of illegitimate recombination hot spot of the retinoic acid receptor alpha gene involved in 15;17 chromosomal translocation of acute promyelocytic leukemia," <i>Oncogene</i> 9:1939-1945 (1994).		
	F13	Tsichlis, P.N., <i>et al.</i> , "A common region for proviral DNA integration in MoMuLV- induced rat thymic lymphomas," <i>Nature</i> 302:445-449 (1983).		
	F14	Unger, R.E., <i>et al.</i> , "Simian Immunodeficiency Virus (SIVmac) Exhibits Complex Splicing for tat, rev, and env mRNA," <i>Virology</i> 152:177-185 (1991).		
	F15	van Ooyen, A., and Nusse, R., "Structure and Nucleotide Sequence of the Putative Mammary Oncogene int-1; Proviral Insertions Leave the Protein-Encoding Domain Intact," <i>Cell</i> 39:233-240 (1984).		

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	G1	Voss, A.K., et al., "Efficiency Assessment of the Gene Trap Approach," <i>Develop. Dynamics</i> 212:171-180 (June 1998).	
	G2	Westphal, E.M., et al., "A System for Shuttling 200-kb BAC/PAC Clones into Human Cells: Stable 23 Extrachromosomal Persistence and Long-Term Ectopic Gene Activation," <i>Human Gene Ther.</i> 9:1863-1873 (September 1998).	
	G3	Xiong, J.-W., et al., "Large-Scale Screening for Developmental Genes in Embryonic Stem Cells and Embryoid Bodies Using Retroviral Entrapment Vectors," <i>Develop. Dynamics</i> 212:131-197 (June 1998).	
	G4	Yoshida, M., et al., "A New Strategy of Gene Trapping in ES Cells Using 3'RACE," <i>Transgenic Research</i> 4:277-287 (1995).	
	G5	Zhou, H., and Duesberg, P.H., "A retroviral promoter is sufficient to convert proto-src to a transforming gene that is distinct from the src gene of Rous sarcoma virus," <i>Proc. Natl. Acad. Sci. USA</i> 87:9128-9132 (1990).	
	G6	Dialog File 351, Derwent WPI English language abstract for FR 2 707 091.	
	G7	Drug Discovery News, "Lexicon Genetics, Inc.," <i>Genetic Engin. News</i> 19:35 (March 1999).	
	G8	PCT International Search Report as provided by the International Searching Authority.	

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